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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/522,373	03/10/00	LOEB	L 16336-000730

020350 HM12/0411
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EXAMINER	
SHIBUYA, M	
ART UNIT	PAPER NUMBER
1635	5

DATE MAILED: 04/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/522,373	LOEB ET AL.
Examiner	**Group Art Unit**
Mark L. Shibuya	1635

☒ Responsive to communication(s) filed on *Oct 10, 2000* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-67* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-67* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-18, 45-50, 63, 64, and 66 drawn to methods of increasing mutation rates of a virus in a cell and in an animal comprising administering an RNA nucleoside analog to a virally infected cell, classifiable in classes 435, 514, subclasses 6 and 440, and 44, respectively.

   II. Claims 19-29, 41-44, and 67, drawn to viral particles comprising RNA nucleoside analogs, cells and pharmaceutical compositions, thereof, classifiable in class 435, subclasses 320.1 and 325.

   III. Claims 30-40, 51-54, 62 and 65, drawn to methods of detecting the mutagenic potential of a ribonucleoside analog, screening for a ribonucleoside analog that is incorporated by a cellular polymerase and a kit thereof, and identifying a mutagenic ribonucleoside analog, and a ribonucleoside so identified, classifiable in classes 435, 536, subclasses 6 and 24.5, respectively.

   IV. Claims 55-61, drawn to methods of making mutagenic ribonucleosides and libraries of mutagenic ribonucleoside, classifiable in class 536 and subclasses 24.5 and 25.3.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions of Groups I, III and IV are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups I, III and IV have not been disclosed as capable of use together and have different functions and effects. The method of Group I for increasing mutation rates of a virus has a different function and a different effect from the method of Group III for detecting the mutagenic potential of a ribonucleoside analog and the method of Group IV for making mutagenic ribonucleosides and libraries, thereof. Likewise, the methods of Group III and Group IV are not disclosed as capable of use together, and have different functions and different effects from each other, because Group III is drawn to identifying mutagenic ribonucleoside analogs, and Group IV is drawn to making mutagenic ribonucleoside analogs.

4. The invention of Group II is unrelated to each of the inventions of Groups I, III and IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the viral particles comprising RNA nucleoside analogs, cells and pharmaceutical compositions thereof of Group II and the nucleoside analog methods and compositions of Groups I, III and IV have not been disclosed as capable of use together and have different functions and effects, because the methods for increasing mutation

rates, and identifying and making mutagenic ribonucleoside analogs have a different function and effect from the viral particles, as evidenced by their different structure.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Claims 10, 21, 31, 42, 46, 55, 57 are generic to a plurality of disclosed patentably distinct species comprising: N^4-aminocytidine, N^1-methyl-N^4-aminocytidine, 3,N^4-ethenocytidine, 3-methylcytidine, 5-hydroxycytidine, N^4-dimethylcytidine, 5-(2-hydroxyethyl)cytidine, 5-chlorocytidine, 5-bromocytidine, N^4-methyl-N^4-aminocytidine, 5-aminocytidine, 5-nitrosocytidine, 5-(hydroxylalkyl)-cytidine, 5-(thioalkyl)-cytidine, cytidine glycol, 5-hydroxyuridine, 3-hydroxyethyluridine, 3-methyluridine, O^2-methyluridine, O^2-ethyluridine, 5-aminouridine, O^4-methyluridine, O^4-ethyluridine, O^4-isobutyluridine, O^4-alkyluridine, 5-nitosouridine, 5-(hydroxyalkyl)-uridine, 5-(thioalkyl)-uridine, 1,N^6-ethenoadenosine, 3-methyladenosine, N^6-methyladenosine, 8-hydroxyguanosine, O^6-methylguanosine, O^6-ethylguanosine, O^6-isopropylguanosine, 3,N^2-ethenoguanosine, O^6-alkylguanosine, 8-oxo-guanosine, 2,N^3-ethenoguanosine, and 8-aminoguanosine. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

8. Claims 9, 11, 12, 18, 20, 24, 27, 28, 29, 32, 33, 34, 39, 48 are generic to a plurality of disclosed patentably distinct species comprising: retrovirus, flavivirus, pestivirus, hepatitis C virus, coronavirus, influenza virus, respiratory syncytial virus, BVDV virus, dengue fever virus, HCV virus, HIV-1, HIV-2, HTLV-1, HTLV-2, SIV, hepatitis A, hepatitis B. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

9. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mark L. Shibuya (SRC),* whose telephone number is (703) 308-9355, and/or to the patent analyst, *Katrina Turner*, whose telephone number is (703) 305-3413.
13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader* may be reached at (703) 308-0447.
14. Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is (703) 308-0196.

Mark L. Shibuya
Patent Examiner
Technology Center 1600
April 9, 2001